



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/560,322 | 09/12/2006 | Birgit Baumgarten | 4-33201A | 4964 |
| 75074 | 7590 | 11/24/2009 | | |
| NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139 | | | EXAMINER LI, RUIXIANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/24/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/560,322 | BAUMGARTEN ET AL. | |
| | Examiner | Art Unit | |
| | RUIXIANG LI | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 08/05/2009 has been entered. Claims 16-18 are added. Claims 5-7 and 10-18 are pending. Claims 7 and 16-18 are under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Withdrawn Objections and/or Rejections

The objection to oath/declaration is withdrawn in view of the new oath/declaration.

The objection to the Disclosure is withdrawn in view of amended specification.

The rejection of claims 1, 2, and 7-9 under 35 U.S.C. 112, first paragraph is withdrawn in view of amended claim 7 and canceled claims 1-4, 8, and 9.

The rejection of claims 1-4 and 7-9 under 35 U.S.C. 112, second paragraph, set forth in the previous office action is withdrawn in view of amended claim 7 and canceled claims 1-4, 8, and 9.

The objection to claims 1-4 and 7-9 for reciting non-elected subject matter is withdrawn in view of amended claim 7 and canceled claims 1-4, 8, and 9.

Art Unit: 1646

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 7 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it refers to the commercial database, Accession No. NM 005282. Claims 16-18 are rejected as dependent claims from claim 7.

Claim Rejections under 35 U.S.C. §102 (e)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(ii). Claims 7, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (US Patent No. 6,919,176 B2, Jul. 19, 2005; 102(e) date: May 7, 2001).

Art Unit: 1646

Yang et al. teach a human G-protein coupled receptor 4 (GPR4) that is 98.7% identical to the amino acid sequence set forth in SEQ ID NO: 3 (see sequence alignment attached to the office action mailed on 05/05/). Yang et al. also teach screening assays for determining inhibitors and activators of the GPCR by measuring a variety of signals, such as second messengers (e.g., cAMP; column 33, the 2nd paragraph; column 34, the 4th paragraph; column 35). Such a second messenger (e.g., cAMP) would be a pH-dependent signal. Thus, the teachings of Yang et al. meet the limitations of claims 7, 17, and 18.

(iii). Claims 7, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Logan et al. (US 2003/0109044 A1, June 12, 2003; 102(e) date: Oct. 16, 2001).

Logan et al. teach a human G-protein coupled receptor, 279, which is 98.7% identical to the amino acid sequence set forth in SEQ ID NO: 3 (see sequence alignment attached to the office action mailed on 05/05/2009). Logan et al. teach screening assays for identifying modulators that bind to 279 receptor or have a stimulatory or inhibitory effect on 279 receptor activity (page 24, paragraph [0282]). Logan et al. teach a cell based assay in which a cell expressing a 279 receptor is contacted with a test compound and the ability of the test compound to modulate the activity of the 279 receptor is determined by monitoring biological messengers or signaling to G proteins (page 25, paragraph [0289]). Such biological messengers or signaling to G proteins would be pH-

Art Unit: 1646

dependent signals. Thus, the teachings of Logan et al. meet the limitations of claims 7, 17, and 18.

(iv). Response to Applicants' argument

Applicants argue that the amended claims require an assay that determines the increase or decrease of pH-dependent signaling from the recited GPR4 related polypeptide. Applicants argue that the specification teaches cAMP formation is dependent signal generated by GPR4 related polypeptides in functional assays. Applicants argue that Yang et al. do not teach the pH-dependency of cAMP formation and is silent regarding the proton-sensing activity of the receptor. Applicants argue that Yang et al. do not teach a screening method that includes the step of determining an increase or decrease in pH dependent signaling of a GPR related polypeptide and, therefore, do not disclose each limitation of the claimed invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while Yang et al. do not teach a proton-sensing GPCR polypeptide, Yang et al. do teach a screening method for determining inhibitors and activators of the GPCR by measuring a variety of signals, such as second messengers. Such a second messenger as cAMP would be a pH-dependent signal. Thus, the teachings of Yang et al. meet the limitations of claims 7, 17, and 18.

With respect to the rejection by Logan et al., Applicants have made the similar argument. These arguments are not persuasive for the same reasons above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
November 22, 2009